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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,067	08/16/2001	David B. Weiner	UPAP0025-100	4038

34136 7590 03/26/2007

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EXAMINER	
KELLY, ROBERT M	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/719,067	WEINER ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10,14-16 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,14-16 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/8/07, and the response of 8/8/06 has been entered.

Claims 2, 5-8, 13, 17-25, 27-30, 32, and 35-39 are canceled.

Claim 9 is amended.

Claims 9-10, 14-16, and 34 are presently pending and considered.

Claim Status, Cancelled Claims

In light of the cancellation of Claims 2, 5-8, 13, 17-25, 27-30, 32, and 35-39, all rejections and/or objection sot such claims are rendered moot, and thus, are withdrawn.

35 USC 112, first paragraph – Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of Applicant's amendments, the rejections of Claims 9-10, 14-16, and 34 under 35 U.S.C. 112, first paragraph, for lacking a fully-enabling disclosure, is withdrawn.

To wit, Applicant has amended the claims to overcome all rejections by removing the limitation "macrophage specific promoter" and canceling other previously-rejected claims.

However, Claims 9-10, 14-16, and 34 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for direct administration to the site proximal to the lymphnode, does not reasonably provide enablement for any method of delivery which transforms cells at the located site. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's claims are broad for the methods of administration. While Claim 9 recites "administering to said individual at said site", which appears to indicate direct administration, Claim 10, which depends from Claim 9, recites several routes of administration, including oral, which appears to be completely indirect, as it is delivered outside the body, into the alimentary tract, rather than into the cells. Further, such indicates that the methods includes any method of administration which is then found to obtain transformation of the cells at the site, and also includes any form of administration.

Applicant's specification is limited to demonstrations of direct intramuscular administration in the Examples. Further, the specification emphasizes the difficulties in transformation of cells at the site due to loss of the plasmid (e.g., p. 38, paragraph), which the Artisan understands to include clearance of the plasmid prior to reaching the target tissues. Such is further demonstrated in that the proteins are not expressed in lymphnodes distant from the site of injection (EXAMPLE 1). This demonstrates further that it is not reasonably predictable that

cells distant from the site of administration would be transformed, and thereby reach the target lymphnode.

Still further, the Art also demonstrates that administrations of plasmid distant from a target tissue are not reasonably predicted to transform the cells of the target tissue in significant numbers, due to clearance by, *inter alia*, the liver (Liu, et al. (1999) Gene Therapy, 6: 1258-66) as well as the fact that the plasmid would necessarily transform cells local to the injection site, thereby precluding their transformation of macrophages at the site desired.

Hence, the Artisan, as demonstrated by the Art and Applicant's disclosure, would not reasonably predict that any particular method of administration of these plasmids would be likely to transforms the macrophages at the site proximal to the lymphnode, but only that direct administration would be efficacious.

Therefore, for any particular site, the Artisan would have to experiment to find those methods of administration which would transform the macrophages of the site. Such amounts to undue experimentation, as it amounts to inventing Applicant's invention for Applicant.

Hence, the claims are limited in their enabled scope to those embodiments provided at the beginning of this rejection.

CONCLUSION

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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